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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,113	07/18/2003	Brent R. Constantz	CORA-001CIP2CON2	4453
24353	7590	08/26/2005	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			BARRETT, THOMAS C	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 08/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/623,113	Applicant(s) CONSTANTZ, BRENT R.	
	Examiner Thomas C. Barrett	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5 and 16-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5 and 16-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11-04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-5 and 16-27 have been considered but are moot in view of the new ground(s) of rejection.

Terminal Disclaimer

The terminal disclaimer filed on January 4, 2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Pat No. 6,379,345, U.S. Pat No. 6,387,071 and U.S. Pat No. 6,622,739 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, and 16-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright (5,135,484). Wright discloses a method using a catheter for demineralization with a solution having a pH of 5.5 or less however fails to disclose the pH specifically ranging from 0 to 1.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to make the pH of the solution of Wright 1.0. Applicant has not disclosed that the lower pH provides an advantage, is used for a particular purpose, or solve a stated problem in comparison to other subphysiological pH levels. The present specification states:

As mentioned above, the pH in the local environment is maintained at a subphysiological level for a sufficient period of time for the desired amount of demineralization of the target lesion to occur. Typically, the pH is maintained at a value that does not exceed about 5 and usually does not exceed about 4, and more usually does not exceed about 3. In many embodiments, the pH of the dissolution solution ranges from between 0 and 1. Within the above range, the pH may be constant or variable over the course of the demineralization procedure, i.e. over the period of time during which the pH of the local environment is maintained at a subphysiological value.

One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either a pH of 5.5 or less, or the claimed pH ranging from 0 to 1, because both ranges overlap and the Applicant fails to disclose any advantage of the claimed range over the range of Wright. Therefore, it would have been obvious to one of ordinary skill in the art to modify Wright to obtain the invention as specified in claims 1, 3, 16-20 and 22-26. As shown below, Wright's invention would still work at a pH of 1.0.

Claims 1, 3, 16-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright (5,135,484) in view of Duoros Jr. et al. (4,196,290). Wright discloses a method using a catheter for demineralization with a solution having a pH of 5.5 or less however fails to disclose the pH specifically ranging from 0 to 1. Duoros Jr. et al. teaches that uric acid crystals precipitate out of solution at a pH of 1 (col. 12, lines 9-

16). It would have been obvious to one of ordinary skill in the art to combine the teaching of a solution having a pH of 1, as taught by Duoros Jr. et al., to the solution as per Wright, in order to keep the uric acid crystals out of solution.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright (5,135,484) in view of Duoros Jr. et al. (4,196,290) as above, in further view of Briskin (5,735,811). Wright discloses a method using a catheter for demineralization however fails to disclose the use of an energy source with the catheter. Briskin teaches a catheter with a vibrational transducer (energy source) which creates turbulence and mechanical disruption, thereby improving the effectiveness of the dissolving agent (Fig. 9). It would have been obvious to one of ordinary skill in the art to combine the teaching of a catheter with a vibrational transducer, as taught by Briskin, to a catheter for demineralization as per Wright, in order to improve the effectiveness of the dissolving agents.

Claims 17-18 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horning et al. (4,013,648). Horning et al. discloses a pH 1.0 hypertonic solution comprising HCl and saturated with NaCl (col. 86, lines 51-66) however Horning et al. fails to disclose a fluid introduction element. It would have been obvious to one of ordinary skill in the art to combine the teaching of a fluid introduction element such as a pipette, eyedropper, funnel etc. as is well known in virtually all chemistry labs to the solution of Horning et al. the motivation to combine being safer handling of solutions. In addition, as noted in the prior office action, a kit is a set of articles or implements used for a specific purpose. The acid and the fluid introduction

element noted above constitute a set of articles or implements used for a specific purpose and are therefore a kit. The instructions are not even claimed as printed. However, if the instructions were claimed as printed matter, all that the printed matter would do is teach a new use for an existing product. Where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability. The cited Horning et al. patent constitutes printed instructions for use of the claimed solution.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (571) 272-4746. The examiner can normally be reached Tuesday-Friday between 9:00 A.M. and 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Thomas Barrett
Examiner
Art Unit: 3738